

INTERNATIONAL STANDARD

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Second edition
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Dental aqueous impression materials based on agar

Produits dentaires hydrauliques pour empreintes à base d'agar-agar



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 1564 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 1564:1976) to which the following changes were made:

- The materials are now classified according to consistencies and purposes.
- The requirement for odour and flavour has been deleted due to lack of an appropriate test. However, it is recognized that the impression material, when handled in accordance with the manufacturer's instructions should have no unpleasant odour or flavour attributable to spoilage or contamination.
- A requirement and an accompanying test for tear resistance replaces the test for compressive strength because the tear test has been judged to be more significant to clinical performance of the agar materials, especially in relation to impressions for fixed prosthodontics.
- Requirements and tests for consistency and extrusion temperatures have been added.
- Designs for the apparatus used in the detail reproduction, compatibility with gypsum, recovery from deformation (permanent deformation), and strain-in-compression tests have been improved in the interest of obtaining more objective test results and to make the tests easier to conduct.
- A requirement relative to antimicrobial characteristics has been added.
- A requirement for manufacturers to identify gypsum products which have been found to be compatible with their impression materials has been added.

- The previous edition specified that most of the pass/fail determinations made for the materials being tested were to be based on averaged values calculated for two or more specimens. Pass/fail determinations made in accordance with this edition are based on the concept that results for each specimen should be compared with the specified performance limit in a separate pass/fail exercise.

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Dental aqueous impression materials based on agar

1 Scope

This International Standard specifies requirements for essential physical properties and other characteristics of impression materials having reversible agar hydrocolloid as a gel-forming ingredient, along with tests specified for determining compliance with those requirements. It also specifies requirements with respect to the manufacturer's instructions, and the essentials for packaging, labelling and marking.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6873:1983, *Dental gypsum products*.

ISO/TR 7405:1984, *Biological evaluation of dental materials*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 gelation temperature: Temperature at which the agar impression material develops the elastic properties which will permit removal of an impression from undercuts in the mouth with only minimal distortion.

3.2 immediate container: Container which is in direct contact with the impression material.

3.3 storing: Conditioning of the material, immediately after liquefaction, needed to reduce the temperature as required prior to its use in syringing, or prior to tempering.

3.4 tempering: Conditioning of the material, after the storing treatment, needed to reduce the temperature of the material as required prior to its insertion into the mouth.

4 Classification by type

Type 1 — High consistency: For making impressions of complete or partial dental arches, with or without the use of syringe-extruded increments of type 2 or type 3 materials.

Type 2 — Medium consistency: For making impressions of complete and partial dental arches, with or without the use of syringe-extruded increments, and also for use as a syringe-extruded material.

Type 3 — Low consistency: For syringe use only.

5 Requirements for characteristics and physical properties

The requirements are given in table 1.

5.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard, but it is recommended that reference be made to ISO/TR 7405 when assessing possible biological or toxicological hazards associated with infection or irritation of normal oral mucosa, or with the concentration of potentially toxic elements or components.

Table 1 — Required property value limits

Type	8.4 Extrusion temperature		8.5 Gelation temperature		8.6 Detail reproduction	8.7 Compatibility with gypsum	8.8 Recovery from deformation	8.9 Strain in compression		8.10 Resistance to tearing
	°C		°C				%	%		N/mm
	min.	max. ¹⁾	min.	max.			min.	min.	max.	min.
Type 1	—	—	37	45	0,02	0,05	96.5	4	15	0,75 ²⁾
Type 2	45	52	37	45	0,02	0,05	96.5	4	15	0,75 ²⁾
Type 3	45	52	37	45	0,02	0,05	96.5	4	15	0,5 ²⁾

1) Maximum temperature the syringed material will transmit to the teeth as stated by the manufacturer [see clause 9 f)] and the maximum temperature that will be registered as the material is extruded to cover the thermometer bulb during the test.

2) These minimum values apply unless a manufacturer claims a higher value, in which case the test result shall not be less than that stated by the manufacturer.

5.2 Homogeneity (Sol state)

When evaluated in accordance with 8.1 and 8.3, the materials shall be free of foreign matter, lumps and granules, and shall exhibit no separation of ingredients that can be observed during extrusion of the materials from their containers or syringes.

5.3 Consistency: types 1 and 2 (Sol state)

When tested in accordance with 8.2, the prepared material shall be capable of being extruded from its immediate container into the specified tray within 30 s.

5.4 Extrudability: types 2 and 3 (Sol state)

When tested in accordance with 8.2, the prepared material shall be of a consistency that will permit the entire increment prepared for syringing to be extruded within 30 s.

6 Sampling

The sample shall be at least 1 500 g of the impression material taken from a single manufacturing batch, along with any devices or accessories specified in the manufacturer's instructions for use with the material. The method of procurement shall be subject to agreements between interested parties.

7 Test methods: basic conditions and procedures

7.1 Specimen preparation

7.1.1 Unless otherwise specified, the materials used for the test specimens shall be prepared and manipulated using the equipment recommended in the manufacturer's instructions (see clause 9).

7.1.2 The materials used for making the test specimens shall be exposed to only one liquefaction treatment and the storage time before specimens are made shall not exceed 1 h.

7.1.3 In instances where the amount of material furnished in a single immediate container, or as a type 3 stick, is less than that needed to form a specimen, it will be necessary to liquefy, store and temper the material in a large single container, such as a modified plastic syringe, which will accommodate the required amount with no risk of dilution.

7.1.4 Gypsum products required for making specimens according to this International Standard shall be evaluated for compliance with the initial setting time test specified in ISO 6873 before use in the tests. After the initial opening of their immediate containers and between openings required thereafter, the gypsum materials shall be stored such that they will not be exposed to moisture contamination.